Opening Statement

H.Westly Clark, M.D., J.D., M.P.H., CAS, FASAM
Director, Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration

Public Hearing

Proposal To Adopt New Federal Regulations for
Opioid Drugs in Maintenance and Detoxification
Treatment of Opiate Dependence

November 1, 1999

As co-presiding officer, along with Dr. David Lepay, Food and Drug Administration, I would like to begin this hearing by thanking all participants for taking the time to present information on the proposed regulations.

Introduction - Before introducing the Federal Panel for this hearing, it is important to reiterate that the purpose of this hearing is to provide an additional opportunity for Federal officials to gather information that will aid in evaluating the proposed rule issued on July 22, 1999. In addition, it will provide an opportunity for panelists representing Federal agencies with interests and responsibilities in this area, to question commentary, to the extent necessary, to clarify issues raised in their comments. It is not the purpose of this hearing to have Federal officials evaluating and making recommendations at this hearing on specific elements in the July 22, 1999, proposed rule. And panelist will not be required to answer question posed by commentary.

Panel - The Federal Panel for today's hearing reflects considerable experience and expertise in the area of Federal oversight and research relating to opioid treatment. Donald R. Vereen, Jr., M.D., MPH, is the Deputy Director, Office of National Drug Control Policy. Ms. Denise Cury, J.D., is with the Drug Enforcement Adminstration's Liaison and Policy Section. Richard Suchinsky, represents the Department of Veteran's Affairs. Steven Zukin, M.D., is the Director of the Division of Clinical and Services Research with the National Institute on Drug Abuse.

Background - The history and process that lead to the publication of the July 27 proposed rule is discussed in some detail in the preamble to the proposal. The initiative to reform the Federal oversight system followed years of study and a report from the Institute of Medicine. In addition, as discussed in preamble, there was extensive deliberation and discussion within the Federal government, the agencies

represented on this panel, on how to proceed in this reform initiative. This study and analysis led to the proposal to issue regulations to establish an accreditation-based regulatory system to replace the current system that relies solely upon direct Federal inspection of treatment programs for compliance with process oriented regulations. The proposed changes are intended to enhance the quality of opioid treatment by allowing increased clinical judgment in treatment and by the accreditation process itself with its emphasis on continuous quality assessment.

Discussion - The July 22 proposed rule was developed by an interagency group. As we proceeded, issues were identified that we thought would especially benefit from additional consideration and comment from individuals outside the government. These special issues were listed in the Hearing notice and relate to the economic impact of accreditation, conflicts of interest for accreditation bodies, the role of States as accreditors. The notice also sought input on hearing procedures, and how multiple detoxification admissions should be addressed. In addition, the proposed rule discussed the growing interest in providing treatment outside the traditional treatment program setting as a way to increase access to treatment in general. How should the Federal opioid treatment standards be modified to accommodate office-based treatment, or, should there be a separate set of Federal opioid treatment standards for office-based treatment. As you know the notice included considerable discussion on medication used for unsupervised use, and proposed some options to address this important issue.

It must be emphasized, however, that today's hearing is not limited to comments on these questions. Indeed, we welcome comments on the entire proposal. Our goal in this effort to solicit as many comments as possible to make this reform initiative as responsive as possible.

We have prepared a list of commentary who file the information specified in the October 19, hearing notice. We ask that the presenter follow the allocated time schedules as close as possible. Attention to the schedule will permit additional time at the end to permit others attending the hearing, who have not file notices to participate, to have an opportunity to present information. We ask that anyone who would like to present information to please sign the form in the back of the room.

Again, I would like to thank everyone for taking the time to participate in this important public health issue.